IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of: Kouchi	Group Art Unit: 1631
Application No.: 10/525,749	Examiner: SKOWRONEK, K.
Filed: February 25, 2005	Confirmation No.: 2075
Atty. File No.: 5553KOU1-1	

For: Biological Information Trend Display Device and Method Thereof

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REPLY BRIEF

Sir:

Appellants hereby submit this Reply Brief in response to the Examiner's Answer mailed July 7, 2010.

(i) STATUS OF CLAIMS.

Claims 1-3, 5-15 and 17-20 are pending, with claim 4 having been cancelled in the 28 December 2007 Amendment, and claims 16 and 21cancelled in the 25 March 2009 Amendment.

Claims 1, 2, 3 and 17-20 are Independent.

The objection to claim 10 was withdrawn in the Notice of Panel Decision From Pre-Appeal Brief Review on 21 January 2010.

Claims 1, 3, 5-8, 10-14 and 17-20 are rejected under 35 U.S.C. §103(a) in view of Schradi et. al (U.S. Patent 5,860,918 – hereinafter "Schradi") in view of Sakaguchi et. al (U.S. Patent 5,807,246 – hereinafter "Sakaguchi") in view of Dia Medical System Kabushiki Kaisha (JP Laid-Open (KOKAI) 1976-787 - hereinafter "JP787").

Claims 2 and 15 are rejected under 35 U.S.C. §103(a) in view of Schradi et. al (U.S. Patent 5,860,918 – hereinafter "Schradi") in view of Sakaguchi et. al (U.S. Patent 5,807,246 – hereinafter "Sakaguchi") in view of Dia Medical System Kabushiki Kaisha (JP Laid-Open (KOKAI) 1976-787 - hereinafter "JP787") and further in view of Nelwan.

Claim 9 is rejected under 35 U.S.C. §103(a) in view of Schradi in view of JP787 and further in view of Manuel et. al (U.S. Patent 6,806,891 – hereinafter "Manuel"), the rejected claims being the subject of this Appeal.

(ii) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL.

1. *Whether claims 1, 2, 3, 5-8, 10-14, 15 and 17-20 are properly rejected under 35 U.S.C. §103(a) in view of Schradi et. al (U.S. Patent 5,860,918 – hereinafter "Schradi") in view of Sakaguchi et. al (U.S. Patent 5,807,246 – hereinafter "Sakaguchi") in view of Dia Medical System Kabushiki Kaisha (JP Laid-Open (KOKAI) 1976-787 - hereinafter "JP787") and whether Claims 2 and 15 are rejected under 35 U.S.C. §103(a) in view of Schradi et. al (U.S. Patent 5,860,918 – hereinafter "Schradi") in view of Sakaguchi et. al (U.S. Patent 5,807,246 – hereinafter "Sakaguchi") in view of Dia Medical System Kabushiki Kaisha (JP Laid-Open (KOKAI) 1976-787 - hereinafter "JP787") and further in view of Nelwan.*

2. *Whether claim 9 is properly rejected under 35 U.S.C. §103(a) in view of Schradi in view of JP787 and further in view of Manuel et. al (U.S. Patent 6,806,891 – hereinafter "Manual"), all of which are the subject of this Appeal.*

(iii) ARGUMENTS.

Regarding the Examiner's assertion that Claims 2 and 15 are not on Appeal, Appellants respectfully submit that it was merely oversight that claims 2 and 15 were not listed in the **"(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL"** section of the Appeal Brief. Clearly in that Appellant argued the merits of Claim 2 in Section 1.2 on page 19 and Claim 15 in Section 1.13 on page 24 of the Appeal Brief, Appellants intended for these claims to be on Appeal. Accordingly, the **"(ii) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL"** section above has been updated to include Claims 2 and 15.

Regarding paragraph 10 of the Examiner's Answer, the Answer points to column 6, lines 63 – column 7, line 14 of Schradi asserting certain claimed features are disclosed. The Examiner also states that "the displaying means further **displays**

biological information determine to as the abnormal biological information in association with information relating to the source of the biological information (emphasis added by the Examiner) is interpreted as an intended use, not as a method step. Nonetheless, as argued above, Schradi et al. discloses the recited limitations."

The Examiner's assertion that the claimed feature is an intended use feature is not supported by law, fact nor the grammar of the claim. The last paragraph of claim 1 defines how the means for displaying displays the time series trend – no reasonable interpretation of this paragraph would lead one to conclude that the claimed wherein feature is an intended use limitation. Moreover, despite the Answer's assertions, the feature is not taught, suggested nor disclosed in any of the relied upon references.

In Schradi, and despite the Examiner's assertions, there is no teaching, suggestion, nor disclosure of the "vertical bars 210" being shown in the same displaying style as the information displayed in the data type displaying area as specifically recited in independent claim 1.

For the Board's convenience, Col. 6 through Col. 7, line 19 of Schradi state:

> The review window contains three channels, one for each physiological parameter monitored: the bradycardia channel 200 has a range from 40 up to 120 bpm (bpm=beats per minute). The desaturation channel 202 has a range from 70 up to 90%. The apnea channel 204 has a range from 0 up to 40 seconds. All channels additionally contain reserved areas for values which exceed the minimum or maximum of their ranges.
>
> As can be seen in FIG. 2, events are shown in the respective channel by vertical bars, cf. e.g. 210. The length of these bars depends on the extent to which the respective parameter, which caused an event, exceeded the threshold associated therewith. For example, the vertical bars for a bradycardia event always begin at the upper edge of the bradycardia channel and, depending on the value which the bradycardia parameter has reached, they extend downwards in the representation. The same applies to the desaturation channel where the vertical bars, which represent events, also extend from the upper edge of the desaturation channel downwards. In the apnea duration channel, the vertical bars extend from a value 0 upwards to an extent that depends on the length of the period of time during which the respiratory

standstill occurred. The representation of the events in this way is one aspect of the present invention.

Clearly, there is no teaching, suggestion nor disclosure of text indicating the source of the biological information is displayed on the data type displaying area in the same displaying style as the time-series trend for biological information which is determined as the abnormal biological information as specifically recited in independent claim 1.

The Examiner's Answer further points to column 3, lines 15-17, column 3 lines, 39-41, column 3, lines 41-50, and column 4, lines 12-18 of Schradi asserting that these portions teach, suggest and disclose text indicating the source of the biological information is displayed on the data type displaying area in the same displaying style as time-series trend for biological information which is determined as the abnormal biological information.

For the Board's convenience, Col. 3, lines 15-17 of Schradi state:

> ...comparing at least one monitored physiological parameter with a predetermined threshold or an alarm limit associated with the respective physiological parameter...

For the Board's convenience, Col. 3, lines 39-50 of Schradi state:

> ...comparing at least one monitored physiological parameter with a predetermined threshold or an alarm limit associated with the respective physiological parameter, and detecting the presence of an event, if a physiological parameter exceeds the associated threshold or alarm limit for a predetermined period of time;
> storing the fact that an event was detected and the parameter value which caused the event, or the parameter value which caused the event and further recorded parameter values, and the respective time at which the event was detected; and
> producing a representation of the events, which were stored during a predetermined, preceding period of time...

For the Board's convenience, Col. 4, lines 12-18 of Schradi state:

> The present invention can, for example, be used for producing a graphical review of the events which occurred within the last 24 hours and which are caused by the occurrence of an apnea, a bradycardia or a desaturation, the events being shown in the form of vertical bars, and the event thresholds or alarm limits being shown in the form of trend lines, i.e. as horizontal lines above the time axis.

Appellants respectfully submit that it is abundantly clear that no reasonable interpretation of any of these paragraphs teach, suggest, or discloses the claimed features.

The Examiner's Answer further asserts that:

> Appellants argue that none of the references relied on disclose or suggest text indicating the source of the biological information is displayed on the data type displaying area in the same displaying style as the time-series trend for biological information which is determined as the abnormal biological information. The argument is not persuasive. Sakaguchi et al. shows in col. 3, line 15-17, measurement values are displayed by steady illumination in green and if the values are not within normal range (i.e. the values are abnormal), they are displayed by flashing red. Sakaguchi et al. disclose the display colors need not be only 2 colors, but may be 3 colors or multiple displays by means of the combination of 3 primary colors (col. 3, line 39-41). Sakaguchi et al. suggests increasing the complexity of the display by increasing the color intensity, changing flashing cycles and including the display of letters, symbols and messages (col. 3, line 41-50). Sakaguchi et al. suggest the combination of display color and illumination mode, different types of data can be displayed in different modes, ambiguity in the display is eliminated, the significance and contents of the display can easily be confirmed by simple observation, and the ease of use of the medical diagnosis and treatment system is enhanced (col. 4, line 12-18). Schradi et al. shows the abnormal events may be linked with a style change in the information describing the source of the biological data by describing that "information concerning the trigger event is

always shown in inverse video" (col. 9, line 17-18) and describing that an alarm limit is the value at which a medical monitoring device triggers an optical and/or acoustical alarm so as to inform a users of the fact that an abnormal or dangerous condition of a patient exists (col. 10, line 26-29). JP787 shows at page 7, line 15-17, that in the event that the data exceeds or drops below preset limits, the comparator can generate an alarm signal to be displayed on the display section. Taking the combined teachings of Schradi et al., Sakaguchi et ai., and JP787 together, the examiner maintains that it would have been obvious to one of ordinary skill to link the style of display of the data trend line for a specific data source with text describing the data source where the motivation to do so is as provided by Sakaguchi et al. to eliminate the ambiguity in the display, to easily confirm the significance and contents of the display by simple observation, and enhance the ease of use of the medical diagnosis and treatment system.

For the Board's convenience, Col. 3, lines 15-17 of Sakaguchi state:

...the process moves to step S17, the measurement values are displayed by steady illumination in green, and if they are not within normal range, in step S18 they are displayed by flashing in red...

and lines 39-50 state:

...the display colors need not be only 2 colors, but may also be 3 colors or multiple color display by means of the combination of 3 primary colors, and in addition and the display can also be made more complex by increasing the color intensity, or changing the flashing cycles, so that when the degree of deviation form normal range is large, this can be distinguished by changing the flashing cycles so that flashing occurs in shorter cycles. Also, in the working example numerical values are displayed, but by using a display device which is able to display letters of symbols other than numbers, the display of various messages, etc., is possible.

and Col. 4, lines 12-18 state:

...specifically, by selecting a steady illumination mode or a flashing mode. Accordingly, by the combination of the display color and illumination mode, different types of data can be displayed in different modes, ambiguity in the display is eliminated, the significance and the contents of the display can be easily confirmed by simple observation, and the ease of use of the medical diagnosis and treatment system is enhanced.

Col. 9, lines 17-18 of Schradi state:

If a combined event is selected, the information concerning the trigger event is always shown in inverse video in the event string box 312. The information concerning the follow-up event is shown in normal video, cf. 314.

and Col. 10, lines 26-29 of Schradi state:

An alarm limit is the value at which a medical monitoring device triggers an optical and/or acoustical alarm so as to inform a user of the fact that an abnormal or dangerous condition of a patient exists.

The Answer's conclusion that "Taking the combined teachings of Schradi et al., Sakaguchi et al., and JP787 together, the examiner maintains that it would have been obvious to one of ordinary skill to link the style of display of the data trend line for a specific data source with text describing the data source where the motivation to do so is as provided by Sakaguchi et al. to eliminate the ambiguity in the display, to easily confirm the significance and contents of the display by simple observation, and enhance the ease of use of the medical diagnosis and treatment system" *is not* supported by the teachings of the references.

At best, the proposed combination as presented in the Examiner's Answer supports measurement values being displayed by steady illumination in green, and if they are not within normal range, they are displayed by flashing in red, wherein the display colors need not be only 2 colors, but may also be 3 colors or multiple color display by means of the combination of 3 primary colors, and in addition and the display can also be made more complex by increasing the color intensity, or changing the flashing cycles, further wherein in the event that the data exceeds or drops below

preset limits, the comparator can generate an alarm signal to be displayed on the display section.

This combination *is not* the claimed combination of features as recited in, for example, independent claim 1.

As previously asserted, and at least on the above basis, since the Examiner's arguments are not sustainable for the independent claims, the dependent claims are also therefore clearly patentably distinguishable therefrom.

This is further evidenced by the Examiner's Answer asserting that Schradi et al. shows the device has means for displaying a time-series trend for each of a plurality of biological information (col. 3, line 26-32). Col. 3, line 26-32 of Schradi et al. recites that "producing a representation of the events, which were stored during a predetermined, preceding period of time, in relation to time, the mode of representation of a respective event depending on the extent to which the parameter causing the event has exceeded the associated threshold of the associated alarm limit."

Schradi et al. does not disclose that the device has means for displaying a time-series trend for each of a plurality of biological information on col. 3, line 26-32.

The Examiner's Answer asserts that Schradi et al. shows information determined as abnormal is displayed in association with information related to the source of information (col. 10, line 26-27). Col. 10, line 26-27 of Schradi et al. recites that an event triggering for a physiological parameter can be set such that it is linked to the alarm generation specified by its associated alarm limit. An alarm limit is the value at which a medical monitoring device triggers an optical and/or acoustical alarm so as to inform a user of the fact that an abnormal or dangerous condition of a patient exists.

Schradi et al. does not disclose that information determined as abnormal is displayed in association with information related to the source of information at col. 10, line 26-27.

The Examiner's Answer asserts that Schradi et al. shows text related to the source of the biological information is displayed in the data display area and in the same style (col. 9, line 47-52). Col. 9, line 47-52 of Schradi et al. recites that in order to make the evaluation of the review representation according to the present invention easier for the user, all items of information which are assigned to one channel can, for example, be shown in one color on the display device, whereas the items of information concerning other channels have different colors.

Schradi et al. does not disclose that text related to the source of the biological information is displayed in the data display area and in the same style at col. 9, line 47-52.

The Examiner's Answer asserts that Schradi et al. suggests in Figure 3 that the displaying means displays a source for abnormal biological information but does not display the source of information that is not abnormal (col. 9, line 15-32). Col. 9, line 15-32 recites that according to the representation of FIG.3A, the cursor 220 is arranged above a combined event, as shown at 310. If a combined event is selected, the information concerning the trigger event is always shown in inverse video in the event string box 312. The information concerning the follow-up event is shown in normal video, cf. 314.

In Schradi, *the source is not displayed* in the event string box 312 or 314. The indication texts of source "BRADY," "DESAT" and "APENA DURAT'N" are always displayed irrespective of abnormal or normal biological information.

Therefore, *Schradi et al. does not suggest* that the displaying means displays a source for abnormal biological information but does not display the source of information that is not abnormal in Figure 3 and col. 9, line 15-32.

As previously emphasized, and in accordance with an exemplary embodiment, the time-series trends for the plurality of biological information are displayed while being overlapped with each other, the text indicating the source of the biological information determined as abnormal being displayed and text indicating the source being displayed in the same style (such as the same color) as the time-series trend for abnormal biological information.

By introducing such features, the necessary space for displaying the plural time-series trends can be reduced and the abnormal biological information can be easily recognized since the text indicating the source and the time-series trends for the biological information are displayed in the same style (such as the same color).

As alluded to above, Schradi discloses text indicating a source, Sakaguchi discloses text showing data and in Sakaguchi, the color of the text is changed to another color when the data is abnormal. JP787 discloses the two time-series trend graphs are displayed overlapping with each other and discloses the color of the time-series trend graph for the biological information will be changed to another color when the biological information is abnormal.

The claimed invention has the features of: a) the text indicating the source of the biological information determined as the abnormal is displayed; and b) the text indicating the source is displayed in the same style (such as in the same color) as the time-series trend for abnormal biological information.

The cited references at least fail to disclose features a) and b).

In Schradi et al., time-series trends *are not displayed* overlapped with each other. The time-series trend for "BRADY" is displayed in the upper region, the time-series trend for "DESAT" is displayed in the middle region and the time-series trend for "APNEA DURAT'N" is displayed in the lower region, that is, each time-series trend is displayed in a *different region* from each other.

As discussed, time-series trends are not displayed overlapped with each other in Schradi et al. Therefore, each time-series trends are clearly distinguished from each other in Schradi et al. In other words, the correspondence between the time-series trend and the text indicating the source can be easily recognized in Schradi due to this relationship.

As recited, for example in independent claim 1, time-series trends are displayed overlapped with each other. Therefore, each time-series trend may not be clearly distinguishable. In other words, the correspondence between the time-series trend and the text indicating the source may not be easily recognized. To avoid this problem, the present invention introduces the feature of the text indicating the source of the biological information determined as abnormal and text indicating the source being displayed in the same style (such as in the same color).

As mentioned above, Schradi et al. could not have been motivated to introduce the feature of the text indicating the source of the biological information determined as abnormal and text indicating the source are displayed in the same style (such as in the same color), because the correspondence between the time-series trend and the text indicating the source can be easily recognized in Schradi. Moreover, Schradi at least fails to teach, suggest or disclose: a) the text indicating the source of the biological information determined as the abnormal is displayed; and b) the text indicating the source is displayed in the same style (such as in the same color) as the time-series trend for abnormal biological information.

Claim 5 is characterized in that the time-series trend for biological information judged as abnormal is displayed in a different style from the time-series trend for

biological information judged as normal, while the time-series trends for biological information judged as normal are displayed in the same style with each other.

The combination of features as recited in claim 5 *are not disclosed* in the references.

Claim 6 is characterized in that the display means displays the source for obtaining biological information at the upper portion when the biological information exceeds the certain level and the source for obtaining biological information at the lower portion when the biological information falls below the certain level.

In JP 787, a part of the color of time-series trend which exceeds upper or lower limit is changed (see FIG. 2).

In JP 787, the text showing the biological information *is not shown.*

Moreover, it would *not* have been obvious to modify JP 787 to provide the text indication area in the upper and the lower region and to selectively indicate the text showing the source in the upper region or the lower region based on whether the biological information exceeds or falls below a certain level.

As for Claim 8, Schradi et al. discloses the device shows the history of the biological information including the abnormal state (see Figs. 3A and 3B).

However, Schradi et al. *does not disclose* the source related information allows one to discriminate the cases: for a case in which current biological information is determined as the abnormal biological information, for a case in which past and current biological information are determined as the abnormal biological information, and for a case in which past biological information is determined as the abnormal biological information while current biological information is not determined as the abnormal biological information.

As for Claims 10, 11 and 15, these claims depend on Claim 1. The Examiner's Answer asserts that Schradi et al. shows the pairing of a data trend with an indicator of the source of the data relying on Figure 2 elements 200, 202 and 204. The Examiner asserts that Schradi et al. shows in Figure 2 that the data considered as normal is presented in the same style which is linear and JP 787 shows that in Figure 2, data considered normal is presented in the same style for all normal data.

The Examiner asserts that Nelwan et al. shows the data acquisition process has been developed to detect and process certain events in the incoming data.

The claimed invention has the features of: a) the text indicating the source of the biological information determined as the abnormal is displayed; and b) the text

indicating the source is displayed in the same style (such as in the same color) as the time-series trend for abnormal biological information.

Neither Schradi nor Nelwan disclose features a) nor b).

As for Claim 13, the Examiner asserts that JP 787 shows the trend line changes color. However, JP 787 at least *does not disclose*: a) the text indicating the source of the biological information determined as the abnormal is displayed; and b) the text indicating the source is displayed in the same style (such as in the same color) as the time-series trend for abnormal biological information.

As for Claims 17-20, the Board is respectfully directed to the arguments above in relation to Claim 1.

As for Claim 9, Claim 9 is characterized in that the inner indication area is used for showing the current abnormal state and the outer indication area is used for showing the past abnormal state. The Examiner pointed out that Manuel et al. shows the dynamic display automatically provides an immediate change of status allowing the operator or user to have instant knowledge of the status of his automatic batch operation and furthermore the ability to use the toggle button and rearrange the priorities as determined by any immediate needs (col. 9. line 14-20).

Manuel et al. *does not disclose* that the inner indication area is used for showing the current abnormal state and the outer indication area is used for showing the past abnormal state.

One exemplary advantage of the present invention is that historical status can be easily recognized by the user.

In that that no reasonable interpretation of any of the relied upon paragraphs teach, suggest or discloses the claimed features, the all claims are in condition for allowance.

Conclusion

Appellants respectfully submit:

the cited references, taken either alone or in combination, fail to teach or suggest every claimed feature,

a *prima facie* cases of obviousness has not been established,

the Office Action and Examiner's Answer include arguments not supported by the references, and

the technical conclusions are neither based in fact nor are technically accurate.

The Board is therefore respectfully requested to overturn the above rejections and pass the Application to issuance.

The Commissioner is hereby authorized to charge to deposit account number 19-1970 any fees under 37 CFR § 1.16 and 1.17 that may be required by this paper and to credit any overpayment to that Account. If any extension of time is required in connection with the filing of this paper and has not been separately requested, such extension is hereby petitioned.

Respectfully submitted,

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